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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,297	12/02/1999	ROGER PETRUS GEREBERN VANDECRUYS	JAB-1282	9783

7590 02/19/2004

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EXAMINER
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JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/445,297

### Applicant(s)

VANDECRUYS, ROGER PETRUS  
GEREBERN

### Examiner

Robert M. Joynes

### Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2, 4-16, 20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 1, 3, 17-19 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 4-16, 20 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

Receipt is acknowledged of applicants' Request for Continued Examination filed on November 26, 2003.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 4-16, 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiesi et al. (US 5855916) in combination with Badwan et al. (US 5645131) or De Sousa Goucha Jorge (EP 0689844 A1, hereafter "844"). Chiesi teaches an inclusion complex of a drug, cyclodextrin and an acid that can be formulated into dosage forms (Col. 1, lines 55-63). The cyclodextrin used can be a  $\beta$ -cyclodextrin, more specifically hydroxypropyl- $\beta$ -cyclodextrin (Col. 1, lines 61-63; Col. 3, lines 15-22). The acids can be organic acids such as citric acid (Col. 2, lines 13-30). Chiesi does not expressly teach the solid pharmaceutical composition and the inclusion of a polymer.

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Badwan teaches poorly water-soluble active agent compositions comprising, a cyclodextrin, a water-soluble acid, and a water-soluble organic polymer wherein, except for the water-soluble acid, the amounts of these ingredients are within the instant ranges (Col. 4, lines 6-67, Col. 5, lines 25-43, 50-63, Example 3, Part B Tablet). Badwan teaches the pharmaceutical tablet formulation for cyclodextrin/acid/drug complexes.

'844 teaches poorly water soluble active agent compositions comprising, a cyclodextrin, a water soluble acid, and a water soluble organic polymer wherein, except for the water soluble acid, the amounts of these ingredients are within the instant ranges (Page 2, lines 44-57; page 3, lines 1-24; Example 7).

None of the references expressly teach the exact concentration ranges set forth in the instant claims. With respect to the claimed concentrations, absent a clear showing of criticality, the determination of particular concentrations is within the skill of the ordinary worker as part of the process of normal optimization.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a solid pharmaceutical composition including a drug cyclodextrin, an acid, and a polymer. Chiesi teaches the cyclodextrin/acid/drug complex that can be formulated into pharmaceutical compositions with polymer. Badwan and '844 teach pharmaceutical compositions comprising such complexes and polymers. The release profile recited is also a parameter that is within the skill of the ordinary worker during normal optimization. These parameters are tailored to the drug being administered and the host to which it is administered.

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One of ordinary skill in the art would have been motivated to do this to provide a suitable pharmaceutical composition of a sparingly water-soluble drug in complex with cyclodextrin and an acid wherein the solubility of the drug is increased.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

Applicant's arguments with respect to claims 2, 4-16, 20 and 22 have been considered but are moot in view of the new ground(s) of rejection.

### ***Correspondence***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Joynes  
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Art Unit 1615

  
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